	ΕP	Α	U	nited St	Washin	gton, DC 20460		Work Assignment Number 3-01						
				Work Assignment					Other Amendment Number:					
Contract Nu				Contra	Contract Period 08/02/2012 To 08/01/2016				Title of Work Assignment/SF Site Name					
EP-D-12-050 Base					Base Option Period Number 3					WA 3-01 (Water/Human Health)				
Contractor	opening decident and paragraph of contract 3000													
Westat, Inc. 1.1, 1.2, 2.1,									2.3, 2	.4, a	and 2.5			
Purpose:	Į	X Work Assi	gnment		Work Assignment Close-Out				Period of Performance					
	[Work Assi	ignment Amend	ment	Incremental Funding									
Work Plan Approval									From 08/02/2015 To 07/29/2016					
Comments: WA 3-01 Water and Human Studies: The Contractor shall perform the activities in Contractor shall not duplicate any work previously performed or incur any cost p										the attached Statement of Work. The				
work Assignment performed under this or the previous Contract (EP-D-07-109).														
Superfund Accounting and Appropriations Data											X	Non-Superfund		
SFO (Max 2) Note: To report additional accounting and appropriations date use EPA Form 1900-69A.														
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Work Assignment Manager Name Edward Hudgens Br									ranch/Mail Code:					
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Work Assignment Form. (WebForms v1.0)

3-01: Support for Water and Human Health Studies WORK ASSIGNMENT STATEMENT OF WORK

Period of Performance: The Period of Performance for this Work Assignment is from date of issuance to July 29, 2016.

I. Background and Objectives

This statement of work is designed to continue the efforts begun during the previous Work Assignments on this (Contract EP-D-12-050, WA 0-01, WA 1-01 and WA 2-01) and previous Epidemiology Support Contracts (Contracts EP-D-07-109 and 68-D-02-062). Westat, Inc. shall not duplicate work performed for these earlier work assignments and shall utilize materials previously prepared as templates for future work. In particular, Westat shall take full advantage of the Quality Assurance Project Plans, Data Management Plans, Database Documentation, Statistical Recommendations and Deliverables developed / submitted previously.

The Environmental Public Health Division (EPHD) conducts clinical and epidemiological research to improve the understanding of human health risks associated with exposure to drinking water contaminates and pathogenic organisms. Epidemiologic investigations study humans in less rigidly controlled, more natural settings by field studies or analysis of existing data. Biomarker methods for exposure, dose and susceptibility will be developed for and applied to a range of health effects including cancer, reproductive effects, cardiovascular disease, and respiratory effects. Laboratory analyses are used to improve assessments of exposure, biologically relevant doses, adverse biological or health effects, as well as to investigate mechanisms linking these phenomena. Studies are frequently designed and analyzed so as to characterize the similarities or differences between effects observed in humans and animals or in vitro systems; the data are then used by the Agency for risk assessment in the absence of human data. Investigations conducted by this division frequently involve collaborations within and outside the Agency, and emphasize interdisciplinary approaches that integrate complex data from existing records, questionnaires, clinical, and laboratory studies.

Database management, review of the results of previous statistical requests, statistical data analyses, spatial analyses, peer reviews of draft documents and review of the scientific literature are fundamental components for these activities. Additionally, a literature review is a significant component of any research paper submitted for publication in a peer-reviewed journal. Such a review may include studies from many scientific disciplines, including epidemiology, toxicology, ecology, exposure assessment, dosimetry and hydrology.

In addition to steps listed above, manuscript preparation requires the drafting of data tables and figures, and report or journal article sections including introduction, methods and materials, results, discussion, conclusions, acknowledgements, and literature cited. The EPA will provide materials such as data, outlines and rough drafts of manuscripts to be used as the basis for a literature review and final manuscript drafting.

The main objectives of this work assignment are to support various Water and Human Health studies by analyzing and preparing data and materials for publication or the support of field collection efforts.

II. Task Descriptions

Task 1: Editing, Graphics and Statistical Support for the Second Journal Article Describing the Results of the Nevada Arsenic Study

In previous Work Assignments, the Contractor provided statistical, editorial and graphics support for a second manuscript that presents results from the Nevada Arsenic Study. This article is intended for submission to Environmental Research. During the previous Work Assignments (1-01 and 2-01), the Contractor provided materials which were incorporated into a draft manuscript for internal EPA technical review. During this Work Assignment, the Contractor shall provide similar support as revisions are made to this draft manuscript in response to journal peer reviewer comments. The EPA anticipates that there will be changes in the number or types of graphics that the Contractor has previously provided, which were incorporated into the draft manuscript. While the EPA does not anticipate the need for reanalysis of the data, the Contractor shall be prepared to reanalyze the data in response to reviewer comments. Such reanalysis work could require changes be made to previously provided graphics or to the existing study database. If changes are made to the existing database, the Contractor shall document these changes in the data documentation and be prepared to deliver the database and supporting documentation files to the EPA. The Contractor shall prepare publication quality versions of the graphics. These versions of the graphics may be required prior to submitting the article to the journal and / or after the response to journal peer reviewer comments has been completed. The Contractor shall review drafts and shall provide comments to improve the editorial quality, clarity and / or validity of the scientific conclusions. The Contractor shall review previously submitted statistical methodology sections for accuracy and completeness, and ensure that their methodology sections are in agreement with the other text within the draft articles. The major goal of this Task is to produce a paper that has been accepted for publication.

All programming documentation is due at the end of this Work Assignment. This includes copies of all statistical programs, statistical code and/or logs of output. The EPA may require the Contractor to provide the programming code used for specific data analysis or quality assurance tasks prior to the end of the Work Assignment for EPA review and QA activities.

The Contractor shall maintain liaison with the WACOR through conference calls, at an agreed upon interval, regarding the status of the activities within this Task. The Contractor shall prepare Agendas for the conference calls, distribute the Action Items and distribute Action Item updates during weeks without conference calls. Copies of all deliverables shall be sent to the WACOR, the COR and the CO (as necessary).

Task 2. Task to Complete the Swimmer Interview and Saliva Health Study (SwISH) Study

The Contractor shall complete a field study at Washington Park Beach, Michigan City Indiana for the outlined subtasks below, using the protocols, procedures, approvals, and documents prepared as part of the SwISH Planning Task (WA 2-01, Task 3) and the SwISH Implementation Task (WA 2-01, Task 6). The Contractor shall enroll participants on Sunday, August 2, 2015. The enrollment goal for the overall study is 750 individuals over the study duration of 6 weekends. The Contractor shall attempt to meet this enrollment goal on the final day. The Contractor shall be prepared to conduct an additional weekend of enrollment if this goal is not met on August 2.

Beach Interviewing:

The Contractor shall provide trained staff to administer questionnaires to household units (as defined below) at the Washington Park Beach, Michigan City, Indiana study site. The Contractor shall use the paper beach questionnaire developed during the Planning Task to accomplish survey sampling of beach goers. These questionnaires shall be conducted in English. The Contractor shall provide trained staff to assist with saliva sample collection.

The eligibility requirements for this study shall be:

- 1. Must have been present on the beach strand area during the day of the survey.
- 2. Households shall be enrolled. A household is defined as at least one adult and one child under the age of 18 years. No single person households shall be enrolled.
- 3. Households shall not be allowed to participate a second time.

The Contractor shall use the methodology and procedures they have previously used in this study to recruit and select households for enrollment. The final day of data collection at the beach site, a sampling of households shall be undertaken for up to six hours a day between approximately 12:00 noon and 6:00 PM local time (Central Time Zone). These times are subject to change to accommodate local park regulations, events and beach goer behaviors. The Informed Consent, beach interview, and initial saliva sample collection (S1) shall be conducted at study stations located in or near the beach entrance/exit point as previously approved by the EPA. The Contractor shall provide required furniture, permits, access approval, equipment, and supplies to complete this Task. The Contractor shall engineer the stations so that all Informed Consent forms and questionnaires are secure and utilize a filing system that maintains data security and incomplete questionnaire confirmation.

The Contractor shall obtain written consent from participants by distributing and discussing the approved Consent Form. Adults 18 years of age and older shall be provided a consent form to review and the Contractor shall be present to answer questions about the study. Unaccompanied minors (under 18 years of age) or households of single individuals shall not be eligible for enrollment. Parents will provide consent for children under 7, and will provide permission for all children under the age of 18. While the adults and adolescents are reading and signing their consent and assent forms, the Contractor shall read the assent form to them and to any children age 7-14. No children below the age of 1 shall be enrolled in this study.

The Contractor shall distribute follow up questionnaire documents developed during the previous Tasks and pre-labeled saliva collection kits to participants for the collection of information 10 –

12 days after their enrollment (S2 sample and required interpretation information). The number of materials shall be the same as the number of participants that were present on the beach that day.

The Contractor shall work sample on this date except in the case of inclement weather conditions, beach management closure or technical direction by the EPA (having obtained the required sample size or inability to obtain the necessary sample size are examples reasons for early termination of the study).

Data Entry:

The Contractor shall enter all beach interview questionnaire forms into an electronic format using the procedures that were approved during the Planning Task. The Contractor shall check for accuracy using accepted methods of quality assurance (QA) to check for errors. The Contractor shall use quality assured Beach Interview data for reminders and for saliva collection kit distribution.

Incentive Distribution:

The Contractor shall provide nonmonetary incentives to households upon completion of Beach Interview / S1 saliva sample collection. The value of these incentives shall be \$15 per individual that provided information and a S1 sample. The Contractor shall distribute monetary incentives to each household upon completion of their participation for each collection of saliva samples (further detailed below). The Contractor shall distribute letters of completion of the study, thanking the participants.

Production Reports:

The Contractor shall provide weekly production reports that summarize the daily completion rates to the USEPA by the close of business on Wednesday after a data collection weekend. The Contractor shall submit the production reports for all data collection days. These reports shall be formatted to work in Excel 2013.

Comprehensive Database:

The Contractor shall complete a comprehensive database that includes all data collected from beach interviews. The Contractor shall submit this database in the format that has been approved by the EPA. The Contractor shall submit this database with a beach identifier numbers for all data. The Contractor shall submit a report for this comprehensive database including, but not limited to, detailed explanation of database use, documentation of changes made over the course of the Task, and detailed definitions of variable names.

The Contractor shall be prepared to enter data from the follow up (S2) questionnaire and add it to the comprehensive database. The Contractor shall be prepared to add these variables to the documentation required above.

Transfer and Ownership of Project-Generated Materials:

The Contractor shall transfer all project-generated products to the USEPA at the completion of this Task. Products such as, but not limited to, data, programs, databases, reports and materials created under this work assignment belong to the USEPA. These products shall be transferred

electronically, when appropriate. Otherwise, products will be shipped to the Environmental Public Health Division in Chapel Hill, NC. Data or products are not to be distributed to any other entities.

Safety Protocol:

The Contractor shall use the safety plan previously created for the field work in this field project.

Quality Assurance and Quality Control:

This project shall utilize a work plan with quality assurance controls as a QAPP. The combination Work Plan and QAPP shall be approved by USEPA and implemented as written. In addition, any data forms developed by the Contractors must be approved by USEPA for quality assurance purposes. The QAPP will be considered draft and updated as required during the course of this work assignment.

Other Records:

Various other documents and records (e.g., SOPs, reports) are discussed in this document in appropriate sections. The EPA reserves the right to request copies of any documents and records from the Contractors that could affect this project. Any records that are received, and any records generated by the Contractor shall become part of the overall project file.

Saliva Samples:

Saliva samples shall be collected from active study participants at the beach using a simple sponge with a handle (S1). Study participants includes persons from households who are actively and successfully participating in the current questionnaire process. Households that are not able to complete the questionnaires successfully will become ineligible for the saliva collection. Participants will be provided with additional, pre-labeled saliva sampling kits in prepaid mailing kits so they can collect and return their samples to the EPA 10 - 12 days after their beach enrollment (S2). The Contractor shall contact households to remind them of items such as, but not limited to, it is time to collect their samples, it is time fill out their questionnaires, and how to replace lost kits. The Contractor shall distribute additional saliva sampling materials in prepaid mailing kits approximately 4 weeks after the receipt of the S2 sample (S3). The initial saliva sample (S1) goal for the entire study is 750 individuals at the beach.

The study targets and offers enrollment to all eligible beachgoers during the time when interviewers are available at the beach site. Beachgoers shall be informed that the study is taking place and asked if they would like to participate in a survey that includes a saliva sample. The Contractor shall briefly describe the study emphasizing the following points: 1) three samples will be collected, today, after 10 days, and after six weeks, and tested for germs that cause gastrointestinal and other illness; 2) sample collection is simple and takes about a minute and; 3) they will be reimbursed for each sample and won't incur any costs for shipping. The Contractor shall distribute gift cards, money orders or like gift after collecting the initial saliva sample at the beach area. The incentive shall be equal to \$15 per sample. For example, a household providing 3 saliva samples would receive the equivalent of \$45. The second saliva collection from that household should be \$15 per sample (household of 3 would receive \$45). The second collection kit shall include a self-administered questionnaire of questions that will be used to interpret the

analysis results for the saliva sample. The self-administered questionnaire shall be labeled with the participant's first name, age and study ID number. The Contractor shall instruct participants on how to complete the questionnaire. The incentive shall be equal to \$10 per completed questionnaire (household of 3 would receive \$30). The third saliva collection from that household should be \$15 per sample (household of 3 would receive \$45). The Contractor shall ship all saliva samples from the field to the US EPA in Chapel Hill, NC, Attn: Elizabeth Sams, 104 Mason Farm Rd., Chapel Hill, NC 27514. All samples shall be shipped with appropriate containers and refrigeration. The Contractor shall email the tracking numbers to sams.elizabeth@epa.gov and hudgens.edward@epa.gov. The Contractor shall include all shipments with the shipment logs and chain of custody forms that have been approved by the EPA. The Contractor shall use the address above for all prepaid, return shipments from study participants.

The Contractor shall maintain liaison with the EPA through conference calls, at an agreed upon interval, regarding the status of the activities within this Task. The Contractor shall prepare Agendas for the conference calls, distribute the Action Items and distribute Action Item updates during weeks without conference calls. Copies of all deliverables shall be sent to the WACOR, the COR and the CO (as necessary).

Task Final Report:

The Contractor shall provide a final work assignment report that includes overview of field procedures, field implementation analysis, training and recommendations for improvement, and assessment of technology.

Task 3: Statistical and Technical Support for Fish Advisory Analyses

Background

This task provides for statistical and technical support related to the EPA projects initiated under Task 4 of WA 2-01.

Scope of Work and Specific Task

Subtask 1: Guidance on Conducting Fish Consumption Surveys

The Contractor shall provide additional support related to the development of the guidance document.

Specific areas of support shall include:

The Contractor shall develop a response to peer review (peer review to be conducted under a separate contract) and develop a revised draft of the guidance document based on the comments received from the peer reviewers

The Contractor shall conduct a review of the peer-reviewed draft document by state and tribal advisory programs, including distribution of the document, collection of comments, and incorporation of comments in the guidance document.

Subtask 2: NHANES and Related Statistical Analyses: PBDEs, Arsenic and PCBs Analysis

- Based on comments provided by the EPA, the Contractor shall revise and update the document and manuscript titled "Time-Trends in NHANES Blood Mercury." Westat will prepare a manuscript for publication in a peer-reviewed journal of the study.
- Based on comments provided by the EPA, the Contractor shall revise and update the NHANES based trends analyses for PBDEs, Arsenic, and PCBs. Westat will also prepare a manuscript for publication in a peer-reviewed journal of these studies.
- The Contractor shall be prepared to perform additional related analyses associated with NHANES, fish consumption and/or chemical levels in fish and/or humans.

Westat will update the QAPP developed under WA 2-01; the Contractor shall provide an explanation of QA to be performed to ensure the usability and accuracy of the data for its intended purposes. The Contractor shall provide an explanation of the independent function of the project QA officer and how QA shall be performed independently. Additionally, the QAPP shall be updated to show the inclusion of the addendum and a QAPP revision history page to be included following the signature page. The Contractor shall ensure and document all activities in accordance with Agency guidance and in compliance with EPA metadata standards. All deliverables shall include a summary describing compliance with the QAPP. The Contractor shall ensure: (1) the products developed under this work assignment comply with the Information Quality Guidelines (IQG) and (2) the IQG checklist is completed for each deliverable, with all supporting documentation for each checklist item, before the final materials are produced.

The Contractor shall maintain liaison with the EPA through conference calls, at an agreed upon interval, regarding the status of the activities within this Task. The Contractor shall prepare agendas for the conference calls, distribute the action items and distribute action item updates during weeks without conference calls. Copies of all deliverables shall be sent to the WACOR, the COR and the CO (as necessary). The EPA anticipates additional work on this project that will not occur during this contract year and has not been described above.

III. Deliverables

Special reporting requirements include documentation of all sources and contacts so as to fully reference the sources of all information. The Contractor shall submit to the Work Assignment Contracting Officer's Representative (WACOR) the following deliverables:

Task 1. Deliverable 1.

A detailed Work Plan, in response to the Task within this Work Assignment, shall be <u>due 20</u> calendar days from the effective date of this Work Assignment for review by the WACOR. As

part of this Work Plan, the Contractor shall also prepare a financial plan and cost estimate for accomplishment of the Task within this Work Assignment. The Contractor shall also supply relevant information on the roles and responsibilities of any subcontractor. The content of the detailed Work Plan shall be in accordance with the terms of the contract and responsive to the requirements of this Work Assignment. The Work Plan shall serve as the QAPP, except for individual Tasks noted above, for this Work Assignment. The QAPP will be considered draft and updated as required during the course of this work assignment.

Task 1. Deliverable 2.

The Contractor shall prepare a final report summarizing all analyses, recommendations, reports, or comments provided during the Period of Performance of this Work Assignment. The final report shall provide documentation for any electronic data sets that may have been generated. Updated versions of any amended databases, data dictionaries, data sets, programs or documents, as well as all graphics and tables generated during the Work Assignment, are due at the completion of the work assignment and in a format that has been approved by the WACOR. Copies of the Monthly Reports, conference call Agendas and the agreed upon Action Items shall be included as documentation of the Task's and the overall Work Assignment's course and progress. All programming documentation is due at the end of this Work Assignment. This includes copies of all statistical programs, statistical code and/or logs of output. The EPA may require the Contractor to provide the programming code used for specific data analysis or quality assurance tasks prior to the end of the Work Assignment for EPA review and QA activities. This report shall include suggestions for potential future work or improvements to the deliverables for any Task that has not been completed during the Period of Performance of this Work Assignment. A draft report is due 14 calendar days before the end of the Work Assignment. A final report, incorporating any EPA comments, is due at the end of the Work Assignment. Files submitted on CD or DVD shall have an accompanying Table of Contents in a format that has been approved by the WACOR.

The Task 3 section of the Final Report shall be provided to the EPA in electronic and paper formats, including one (1) CD per deliverable provided in PDF format; one (1) CD per deliverable in original software (all software shall be cleared by the WACOR prior to use); one (1) camera-ready copy of each product (unless otherwise requested); and four (4) bound paper copies of all reports. All documents shall be in web-ready format and 508 compliant. Meeting summaries shall be provided via email to the EPA and included as part of the folder in the overall Work Assignment Final Report. The Contractor shall certify in writing for each product that all electronic and paper copies are identical mirror images.

Task 1. Deliverable 3.

The Contractor shall review the draft of the Nevada Arsenic Study Metabolism and Genetic Polymorphism Paper and shall provide comments to improve the editorial quality, clarity and / or validity of the scientific conclusions within 21 calendar days of receipt, prior to its submission to a peer reviewed journal. The Contractor shall review previously submitted statistical

methodology sections for accuracy and completeness, and ensure that their methodology sections are in agreement with the other text within the draft article. If changes to the methodology sections are necessary, the Contractor shall document any changes and the rational for the change. The Contractor shall review existing data tables and figures and prepare new, publication quality versions, when necessary, for the manuscript.

Task 1. Deliverable 4.

In response to the journal's peer reviewers' comments, the Contractor shall review the draft of the Nevada Arsenic Study Metabolism and Genetic Polymorphism Paper and shall provide comments to improve the editorial quality, clarity and / or validity of the scientific conclusions within 21 calendar days of receipt. The Contractor shall review previously submitted statistical methodology sections for accuracy and completeness, and ensure that their methodology sections are in agreement with the other text within the draft article. If changes to the methodology sections are necessary, the Contractor shall document any changes and the rational for the change. The Contractor shall review existing data tables and figures and prepare new, publication quality versions, when necessary, for the manuscript.

- **Task 2. Deliverable 5.** The Contractor shall distribute incentives at the time of successful completion of enrollment (initial interview and S1 samples). The Contractor shall send checks to participants and Participation Status letters to each household after each subsequent, successful saliva sample or questionnaire submission (10 12 days, and 6 weeks). The Contractor shall keep a record of all payments and submit this list at the completion of this Task.
- **Task 2 Deliverable 6.** Production Reports are due by the close of business the Wednesday following the weekend data collection.
- Task 2 Deliverable 7. The Contractor shall provide a comprehensive database for this study 21 calendar days after the completion of all sample / data collection activities. The Contractor shall submit a report for this comprehensive database including, but not limited to, detailed explanation of database use, documentation of changes made over the course of the Task, and detailed definitions of variable names.
- **Task 2 Deliverable 8.** The Contractor shall ship S1 saliva samples collected on August 2, 2015 to EPA within three days of saliva sample collection.
- **Task 2 Deliverable 9.** The Contractor shall submit a draft Final Report for this Task, of no more than 5 pages in length (excluding attachments), describing the results of this study 35 calendar days after the completion of all sample / data collection activities. The EPA will have 14 calendar days to review and provide comments. The Contractor shall prepare a Final Report incorporating any EPA comments within 14 calendar days. The Contractor shall include the report for this Task as part of the Final Report for this WA (Deliverable 2).
- Task 3 Deliverable 10. The revised QAPP required for this Task shall be due within 14 calendar days of the receipt of this Work Assignment. The final QAPP shall be due at the end of

the Period of Performance of this Work Assignment. The IQG checklist shall be due at the completion of each final deliverable required by the Work Assignment.

Task 3 <u>Deliverable 11</u>. Within 5 calendar days of receiving and incorporating EPA comments on the existing draft Development of Guidance on Conducting Fish Consumption Surveys document, the Contractor shall provide the document electronically to the state and tribal advisory programs for review and comment. The Contractor shall provide 30 days for review. In consultation with the EPA, the Contractor shall incorporate the state and tribal comments and develop a draft, revised document by the end of the Period of Performance of this Work Assignment.

Task 3 <u>Deliverable 12</u>. For the NHANES Fish Consumption/Contaminant Analysis work, the Contractor shall submit all drafts of the reports, drafts of manuscripts, and the results of any statistical analyses by the end of the Period of Performance of this Work Assignment.

IV. Reporting Requirements

The Contractor shall furnish a copy of the Work Plan, as well as each section of the combined monthly technical and financial progress reports which relate to this Work Assignment directly to the Work Assignment Contracting Officer Representative at the same time progress reports are submitted to the Contracting Officer Representative and Contracting Officer. The work plan shall serve as the QAPP for this Work Assignment.

Special reporting requirements include documentation of all sources so as to fully reference the sources of all information. Deliverables shall be provided in hard copy and electronically on CD-ROM, DVD or via email. Reports shall be written in Word or PDF format, based upon approval from the WACOR. Two copies of the final report shall be provided to the WACOR. A copy to of the final report shall be provided to the COR and CO, upon request.

V. Work Assignment Contracting Officer's Representative Designation

The Work Assignment Contracting Officer's Representative (WACOR) will be:

Edward E. Hudgens Chemist US EPA/ORD/NHEERL/EPHD/EB (MD-58C) Research Triangle Park, NC 27711

Telephone: 919-966-0642 Fax: 919-966-0655

Email: hudgens.edward@epa.gov

The preferred method of contact is by email.

VI. WORK ASSIGNMENT DURATION

The period of performance for this work assignment is from date of issuance through July 29,

VII. NOTICE REGARDING GUIDANCE PROVIDED UNDER THIS WORK ASSIGNMENT

The contractor shall not engage in activities of an inherently governmental nature such as the following:

- 1. Formulation of Agency policy;
- 2. Selection of Agency priorities;
- 3. Development of Agency regulations.

Should the contractor receive any instruction from an EPA staff person that the contractor ascertains to fall into any of these categories or goes beyond the scope of the contract or work assignment, the contractor shall immediately contact the COR or the Contract Officer.

The contractor shall also ensure that the work under each individual work assignment does not contain any real or apparent personal or organizational conflict of interest. The contractor shall certify that none exist at the time the work plan is submitted to the EPA.